

REMARKS

Claims 47-107 were previously submitted for examination. Claims 47-68 and 98-107 were withdrawn from consideration. Claims 1-46 were canceled by the Preliminary Amendment submitted on January 16, 2004 and claims 72-77, 85, 87-91 and 94 were canceled by the March 23, 2007 Amendment. Claims 69, 70, 78, 79, 86, 92, 108-112, 114-119 and 121-126 have been amended, and new claims 128-131 have been added by the present Amendment. Therefore claims 69-71, 78-84, 86, 92, 93, 95-97 and 108-131 are under active consideration.

Support for the amended claims 69, 78 and 92 for reciting an “isolated antibody that specifically binds to a bioactive epitope of a parathyroid hormone (PTH) in PTH₁₋₈ or PTH₁₋₉ sequence” can be found in the teachings in the original application of using a PTH₁₋₈ peptide to purify an anti-PTH antibody (*See e.g.*, the present specification at page 11, lines 7-13), and a whole PTH assay using an antibody that binds to an epitope within PTH₁₋₉ sequence (*See e.g.*, Figure 2 of the present application).

Support for the amended claims 69, 78, 86 and 92 for reciting “said isolated antibody binds to said epitope within a whole PTH with a higher affinity than its binding to said epitope within a PTH fragment selected from the group consisting of a PTH₁₋₈ fragment, a PTH₁₋₉ fragment, a PTH₁₋₁₀ fragment, and a PTH₁₋₃₄ fragment” can be found in an inherent binding property of an exemplary anti-PTH antibody used in the whole PTH assay as described in the present application, *e.g.*, at page 8, lines 24 and 25 of the present specification, and in Figure 11. This inherent binding property is described in Rebuttal Expert Report of Richard A. Lerner, M.D. (Lerner Report) (Exhibit B of the March 23, 2007 Amendment) at paragraph 5, pages 5-8 and Exhibits 2-7 of the Lerner Report.

Support for the amended claims 70, 79, 108-112 and 114-126 and new claims 128-131 can be found in the teachings in the original application and in the inherent binding property of the exemplary anti-PTH antibody used in the whole PTH assay as discussed above for the amended claims 69, 78, 86 and 92.

Accordingly, the present amendments do not introduce any new matter. Entry of the amendments is respectfully requested.

With respect to all amendments and canceled claims, applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Priority

Regarding the priority claim, the Examiner states:

It is noted that Applicant claims priority based on its parent cases, i.e. US 09344039 (now US Patent 6743590) and US 09231422 (now US Patent 6689566). However, due to lack of support from the specification, the current application is accorded priority date based on its filing date, i.e. 1/16/2004 (See below New Matter Rejection).

Applicants respectfully submit that the presently pending claims are entitled to the filing dates to the parent patents, U.S. Patent Nos. 6,689,566 and 6,743,590, for the reasons discussed below as a response to the written description (new matter) rejection.

Rejection under 35 U.S.C. § 112, first paragraph - New matter

The rejections of claims 69, 71, 78-84, 86, 92, 93, 95-97 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement are maintained. The Examiner alleged that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The Examiner maintained the written description (new matter) rejection for the alleged lack of written description of the isolated antibody that specifically binds to a bioactive, three-dimensional epitope of a parathyroid hormone (PTH). Applicants respectfully submit that, as

discussed in the previous responses to the office actions, the present application and parent applications provide an adequate description for the anti-PTH antibody that specifically binds to a bioactive, three-dimensional epitope of a PTH, especially in view of the inherent properties of the exemplary antibodies disclosed in the present application as shown in Rebuttal Expert Report of Richard A. Lerner, M.D. (Lerner Report) (Exhibit B of the March 23, 2007 Amendment). However, to advance the prosecution of the present application, the limitation “three-dimensional epitope” has been deleted in the presently pending claims, and this amendment obviates the alleged lack of written description of the isolated antibody that specifically binds to a bioactive, three-dimensional epitope of a PTH.

The Examiner also maintained the written description (new matter) rejection for the alleged lack of written description of the isolated antibody that specifically binds to an epitope in PTH₁₋₉ sequence. Applicants respectfully traverse this rejection. As discussed in the previous responses, the present application and parent applications provide an adequate description for the anti-PTH antibody that specifically binds to an epitope in PTH₁₋₉ sequence in numerous ways. For example, the present application and parent applications describe a whole PTH assay using an antibody that binds to an epitope within PTH₁₋₉ sequence (*See e.g.*, Figure 2 of the present application and the parent applications).

The Examiner further maintained the written description (new matter) rejection for the alleged lack of written description of a PTH fragment selected from a PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment. Applicants respectfully submit that, as discussed in the previous responses to the office actions, that the present application and parent applications provide an adequate description for an isolated antibody that binds to the recited bioactive epitope within a whole PTH with a higher affinity than its binding to the epitope within a PTH fragment selected from a PTH₁₋₈ fragment to a PTH₁₋₃₄ fragment, especially in view of the inherent properties of the exemplary antibodies disclosed in the present application as shown in the Lerner Report.

The Examiner, however, acknowledged that in view of the inherent properties shown in the Lerner Report, the present application has adequate written description for an isolated antibody

that binds to the recited bioactive epitope within a whole PTH with a higher affinity than its binding to the epitope within a PTH₁₋₈ fragment, a PTH₁₋₉ fragment, a PTH₁₋₁₀ fragment, and a PTH₁₋₃₄ fragment. (The August 19, 2008 Office Action at pages 4-5.) To advance the prosecution of the present application, the presently pending claims have been amended to recite “a PTH fragment selected from the group consisting of a PTH₁₋₈ fragment, a PTH₁₋₉ fragment, a PTH₁₋₁₀ fragment, and a PTH₁₋₃₄ fragment.” Accordingly, this alleged lack of written description (new matter) rejection is obviated by the present amendment.

Therefore, applicants respectfully submit that the present application and parent patents provide an adequate written description for the presently pending claims and the written description (new matter) rejection can properly be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 532212000624. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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